K061488

JUN 30 2006

# Section 7
# Summary of Safety and Effectiveness

| | |
|---|---|
| Trade Name: | CTS-5500/CTS-6600 with C3I40 and L7I50 Transducers |
| Common Name: | Diagnostic Ultrasound System |
| Classification Name: | Ultrasonic Pulsed Echo Imaging System, 90 IYO |
| | (Per 21 CFR section 892.1560) |
| Manufacturer's Name: | Shantou Institute of Ultrasonic Instruments |
| Address: | #77, Jinsha Road, |
| | Shantou SEZ, 515041, China |
| Corresponding Official: | Li Delai |
| Title: | President |
| Telephone: | (86) 754-8250150 Fax: (86) 754-8251499 |
| US Agent: | Bob Leiker/ Consultant /QRS |
| | Dublin, CA 94568 |
| | Telephone: 1-925-556-1302 Fax: 1-866-718-3819 |

Predicate Device: SIUI CTS-485 , K012772

Device Description: The SIUI CTS-5500/CTS-6600 is a portable diagnostic ultrasound system capable of the following operating modes: 2D (B mode), M and B/M. The system is designed for use in linear and convex scanning modes and supports linear and convex transducers. The system has cine review, image zoom, measurements and calculations, printing and recording capabilities. The system consists of probes, main unit, control panel and monitor.

Intended Use: Ultrasonic pulsed echo imaging and measurement for abdominal, pediatric, small organ, cardiac, peripheral vascular applications

Technological Characteristics:

1) Scanning modes: convex and linear scanning
2) Display modes: a) B-Mode (B, 2B) b) M-Mode c) B/M-Mode
3) Grey scale: 256
4) Frequency of probe: 2.5MHz to 9.0MHz

5) Image Display multiple: x1.0, x1.5, x2.0; Shift 2mm step
6) Focusing method: Variable aperture 1-4 focal zone electronic focusing
7) Display range (max):
   Depth 210mm angle 82°(Convex probe)
   Depth 140mm width 50mm (Linear probe)
8) Image adjustment:
   a) Gain: 0 to 99 (digital) b) TGC: 6 steps c) Grey map curve: 8 types
   d) Frame correlation: 4 steps e) Edge enhance: 4 steps
9) M-mode speed:
   Time for full screen scroll: 1, 2, 4, 8 sec
10) Cineloop: 64 frames,continual/single
11) DSC memory capacity: 512x512x8 bit
12) Image display: Left/right, positive/negative
13) Monitor: 10-inch B/W monitor
14) Character display
   a) Patient's ID b) Hospital Name c) Comment
   d) Automatically display items: Date & time, probe frequency, gain and other operating parameters
15) Body marks: 25 types
16) Measurements and calculations
   (a) General measurements and calculations
      2D: Distance, Area, Circumference, and Angle
      M-Mode: Distance, Time, Slope, Heart rate
   (b) Obstetrics measurements: BPD, CRL, FL, AC, HC, GS, VOL, ANG
   (c) Other measurements
17) I/O port
   RS-232C port for transmitting images to PC
18) Dimension: 320(w) x415 (l) x310 (h) mm
19) Net Weight: approx. 11kg for CTS-5500, 10kg for CTS-6600
20) Power Consumption:
   220V±10, 110VA or 110V±10, 110VA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2006

Shantou Institute of Ultrasonic Instruments (SIUI)
% Mr. Bob Leiker
Quality & Regulatory Services
7263 Cronin Circle
DUBLIN CA 94568

Re: K061488
Trade Name: CTS-5500/CTS-6600 Diagnostic Ultrasound Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Number: 21 CFR 892.1560
Regulatory Name: Ultrasonic pulsed echo imaging
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic transducer
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: May 26, 2006
Received: May 31, 2006

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CTS-5500/CTS-6600 Diagnostic Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

Convex Array C3140
Linear Array L7150

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small

Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

## Diagnostic Ultrasound Indications for Use Form

1. System Indications for Use Form

Device Name: CTS-5500/CTS-6600 K061488

Mode of Operation

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | | | | | | | | | | |
| Fetal | | P | P | | | | | | P | |
| Abdominal | | P | P | | | | | | P | |
| IntraOperative (Cardiac) | | | | | | | | | | |
| IntraOperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | | | | | | P | |
| Small Organ (Specify) | | P | P | | | | | | P | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | | | | | | P | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral Vascular | | P | P | | | | | | P | |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

N = new indication P = previously cleared by FDA E = added under Appendix E

Additional Comments: Small organs includes: thyroid, parathyroid, parotid, submaxillary gland, testes and breast

Combined: B/M Mode

Pediatric Comments: Pediatric Intended Uses include: Cardiology, Abdomen, Peripheral Vascular

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Reproductive and Radiological Devices
510(k) Number K061488

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

2. Transducer Indications for Use Form

Device Name: Convex Array C3I40 K061488

**Mode of Operation**

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | | | | | | | | | | |
| Fetal | | P | P | | | | | | P | |
| Abdominal | | P | P | | | | | | P | |
| IntraOperative (Cardiac) | | | | | | | | | | |
| IntraOperative Neurological | | | | | | | | | | |
| Pediatric(Specify) | | P | P | | | | | | P | |
| Small Organ (Specify) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | | | | | | P | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

N = new indication P = previously cleared by FDA E = added under Appendix E

Additional Comments: Pediatric Comments: Pediatric Intended Uses include: Cardiology, Abdomen

Combined: B/M Mode

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061488

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

3. Transducer Indications for Use Form

Device Name: Linear Array L7I50 K061488

**Mode of Operation**

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| IntraOperative (Cardiac) | | | | | | | | | | |
| IntraOperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | | | | | | P | |
| Small Organ (Specify) | | P | P | | | | | | P | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral Vascular | | P | P | | | | | | P | |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

N = new indication P = previously cleared by FDA E = added under Appendix E

Additional Comments: Small organs includes: thyroid, parathyroid, parotid, submaxillary gland, testes and breast

Combined: B/M Mode

Pediatric Comments: Pediatric Intended Uses include: Peripheral Vascular

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Prescription Use (Per 21 CFR 801.109)